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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,613	05/29/2007	Marc Peuker	59109US004	7832
	7590 10/30/200 IVE PROPERTIES CO	EXAMINER		
PO BOX 33427		PAGAN, JENINE MARIE		
ST. PAUL, MN 55133-3427			ART UNIT	PAPER NUMBER
			3728	
			NOTIFICATION DATE	DELIVERY MODE
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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	Application No.	Applicant(s)
	10/598,613	PEUKER ET AL.
Office Action Summary	Examiner	Art Unit
	JENINE M. PAGAN	3728
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	lely filed the mailing date of this communication.  (35 U.S.C. § 133).
Status		
1) ☐ Responsive to communication(s) filed on 29 M 2a) ☐ This action is <b>FINAL</b> . 2b) ☐ This 3) ☐ Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro	
Disposition of Claims		
4) ☐ Claim(s) 1-26 is/are pending in the application. 4a) Of the above claim(s) 11-19 is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-10 and 20-26 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	n from consideration.	
9) The specification is objected to by the Examine 10) The drawing(s) filed on <u>06 September 2006</u> is/a Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction.	re: a)⊠ accepted or b)⊡ objecdrawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.
Priority under 35 U.S.C. § 119  12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of the certified copies of the attached detailed Office action for a list of the certified copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of the certified copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list of the certified copies of the certified copies of the priority documents are copies of the priority documents are copies of the priority documents are copies of the certified copies of the priority documents are copies of the priority documents are copies of the certified copies of the priority documents are copies of the certified copies of the priority documents are copies of the certified copies of the priority documents are copies of the certified copies of the priority documents are copies of the certified copies of the priority documents are copies of the certified copies of the priority documents are copies of the certified co	s have been received. s have been received in Applicati ity documents have been receive ı (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 4/5/2007.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ite

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### **DETAILED ACTION**

1. Applicant's election without traverse of Group I claims 1-10 and 20-26 in the reply filed on 10/10/2008 is acknowledged.

2. Claims 11-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/10/2008.

## **Priority**

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### Information Disclosure Statement

- 4. The information disclosure statement (IDS) submitted on 4/5/2008 is being considered by the examiner.
- 5. The information disclosure statement filed 4/5/2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

# Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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7. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. 112, second paragraph. MPEP 2173.05(q).

### Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 26 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim is an improper definition of a process claim. *Ex parte Dunki*, 153 USPQ 678 (Bd. App. 1967), see MPEP 2173.05(q).

### Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. Claims 1-5, 20-22, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over B. Schwartz (US 3,464,412) in view of M.J. Cohen (US 2,754,590).

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#### Claims 1 and 25: Schwartz discloses:

 a capsule body member 20 providing a main chamber 49, and comprising a dispensing opening 42, and wherein the inner wall of the capsule body member comprises a recessed area 24

- an applicator member 30 being slideably accommodated in said capsule body member 20, said applicator member 30 providing an auxiliary chamber 45, and wherein said applicator member 30 comprises a through-hole 34 extending from the auxiliary chamber 45 to the outer circumferential surface of the applicator member 30
- an activator member 35 being slideably accommodated in said applicator member 30
- through-hole 34 and said recessed area 24 forming a channel between said main chamber 49 and said auxiliary chamber 45 upon activation of said capsule by said activator member 35
- said main chamber 49 and said auxiliary chamber 45 being selectively connectable for fluid communication between said chambers upon activation of said capsule by said activator member 35

#### Schwartz does not disclose:

 movement of said activator member towards said dispensing opening causes movement of said applicator member so that said channel between said main chamber and said auxiliary chamber is formed

However Cohen discloses:

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• movement of said activator member 26 towards said dispensing opening 22 causes movement of said applicator member 26 so that said channel between said main chamber 18 and said auxiliary chamber 17 is formed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the movement of the activator member towards the dispensing opening to form the channel between the main and auxiliary chambers as taught by Cohen instead of the have the movement of the activator member away from the dispensing opening to form the channel between the main and auxiliary chambers, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in

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Claim 2: Schwartz discloses (Fig 1):

the art. In re Einstein, 8 USPQ 167.

 radially extending through-hole 34 in said applicator member 30 is initially covered by the wall of said capsule body member 20

Claim 3: Schwartz discloses (Fig 1):

 radially extending through-hole 34 is located in close proximity to the separation wall 33 of said applicator member 30 separating said auxiliary chamber 45 from said mixing chamber 49

Claim 4: Schwartz discloses (Fig 1):

 through-hole 34 extends essentially perpendicularly to the longitudinal axis of said applicator member 30

Claim 5: Schwartz discloses (Fig 1):

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 through-hole extends essentially at an angle smaller than 90° to the longitudinal axis of said applicator member 30

Claim 20: Schwartz discloses (Fig 1):

a dispensing cannula 21 connected to said dispensing opening

Claim 21: Schwartz discloses (Fig 1):

 the dispensing cannula 21 is integrally formed with said capsule body member 20

Claim 22: Schwartz discloses (Fig 3):

 cannula 44 is rotatably connected to said capsule body member thus providing a valve

According to the Merriam-Webster Online Dictionary the definition of a needle as disclosed in Schwartz Fig 3, is "a slender pointed rod controlling a fine inlet or outlet (as in a valve)".

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the cannula rotatably connected to the capsule body as seen in figure 3 instead of integral as in figure 1, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art.

Nerwin v. Erlichtnan, 168 USPQ 177, 179.

Claim 24: Schwartz discloses (Col 4:48-59):

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 main chamber 49 contains a first, preferably powdery, component of said material, and said auxiliary chamber contains a second, preferably liquid, component of said material

11. Claims 6-10 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over B. Schwartz (US 3,464,412) and M.J. Cohen (US 2,754,590) and further in view of Dragon et al. (US 5,172,807).

Claim 6: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 and 3 except:

separation wall comprise a raised area extending towards said activator member

### However, Dragan discloses (Fig 8):

 separation wall 138 comprise a raised area (see figure above) extending towards said activator member 266

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a raised area included in the separation wall as taught by Dragan, since *Dragan* shows in Fig 8 that such a modification would allow the two substances an area to begin to mix together.

Claim 7: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 and 3 except:

raised area comprises an annular bulge

### However, Dragan discloses (Fig 8):

raised area (see figure above) comprises an annular bulge

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It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the raised area included in annular bulge as taught by Dragan, since *Dragan* shows in Fig 8 that such a modification would allow the two substances an area to begin to mix together in a curvature manner.

Claim 8: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 and 3 except:

 applicator member comprises a sealing element sealing said through-hole of said applicator member against said recessed area of said body member and against the exterior of said capsule

# However, Dragan discloses (Fig 8):

applicator member 266 comprises a sealing element 234 sealing said
 through-hole of said applicator member 266 against said recessed area of
 said body member and against the exterior of said capsule

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the applicator member include a sealing element as taught by Dragan, since *Dragan* states at column 5 lines 35-37 that such a modification would keep the substances separate until ready to combine and use on the patient such as powder and water to mix for cement to fix a filling.

Claim 9: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 and 3 except:

 activator member comprising an activator sealing element for sealing said activator member against said applicator member

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# However, Dragan discloses (Fig 8):

 activator member 224 comprising an activator sealing element 268 for sealing said activator member 224 against said applicator member 266

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the activator member include a sealing element as taught by Dragan, since *Dragan* states at column 5 lines 47-52 that such a modification would keep the substances separate until ready to combine and use on the patient such as powder and water to mix for cement to fix a filling.

Claim 10: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 and 3 except:

 sealing elements are manufactured by a two-component injection molding process together with the capsule body member, the applicator member and said activator member

# However, Dragan discloses (Fig 8):

 sealing elements 234/268 are manufactured by a two-component injection molding process together with the capsule body member, the applicator member 266 and said activator member

In accordance to MPEP 2113, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight. Please note that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.

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The patentability of a product, i.e. sealing elements, does not depend on its method of production, i.e. two-component injection molding process.

In re Thorpe, 227 USPQ 964, 966 (Federal Circuit 1985).

#### Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENINE M. PAGAN whose telephone number is (571)270-3216. The examiner can normally be reached on Monday - Thursday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/J. Gregory Pickett/ Primary Examiner, Art Unit 3728 /Jenine M Pagan/ Examiner, Art Unit 3728

/J. M. P. / Examiner, Art Unit 3728